POCKET FETAL DOPPLER

SONOTRAX-E

MANUAL BOOK

Elitech® TECHNOVISION

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CAUTION

In the United States, Federal law restricts this device to sale, distribution, and use by or on order of a licensed physician.

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Chapter 1 Introduction

1.1 Product Features

Different models have different features as follows.

Functions	SONOTRAX-E
Display	Colour
Backlight	Yes
Built-In Speaker	Yes
Auto-Power Off	Yes
Alkalinity Battery	No
Rechargeable Battery	Yes
Battery Indicator	Yes
FHR Curve	Yes
Probe Detect	Yes
Various Display Modes	Yes
Storage	Yes
Replay	Yes
2.5M Probe	Optional
3.0M Probe	Optional
Earphone	Optional
Carry Bag	Optional

Remark: “Yes” means the device has the function

“No” means the device don’t have the function

“Optional” means can choose this function

1.2 Standard Configuration

No.	Name	Quantity
1.	Main Body	1 pc
2.	Probe	1 pc
3.	Battery	3 pcs

Chapter 2 Appearance

2.1 Main Unit

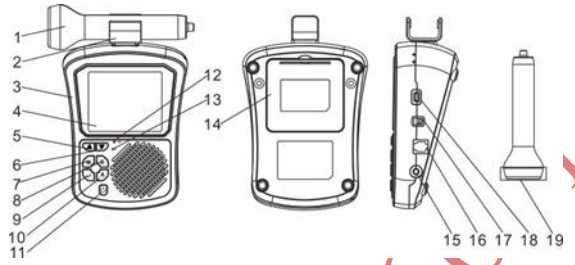

Figure 2.1 Front View

Parts list is as follows;

(1) Probe
(2) Probe Clamp
(3) Main Unit
(4) Display Area
(5) Volume Up Key
(6) Volume Down Key
(7) Menu Key
(8) Freeze Key
(9) Confirm Key
(10) Alarm On/Off Key
(11) Power On/Off
(12) Charging Indicator
(13) Power Indicate Light
(14) Battery Case
(15) Earphone Port
(16) Probe Connection Port
(17) DC Port
(18) USB Port
(19) Water-proof Parts

2.2 Display

The working display of SONOTRAX-E is FHR digital display, like below:

Curve

Parameters and FHR Digit

Large Digit

2.3 Controlling Keys

In main unit configuration, there are five keys as follows.

2.3.1. Menu Key

Press this key to enter into menu setup. When finishing setting parameters, press this key to exit menu setup and enter into work state.

2.3.2. Up Key

When entering into menu setup, press this key to select sub-menu or parameters from down to up.

When the device is working, press this key to increase speaker volume.

2.3.3. Down Key

When entering into menu setup, press this key to select sub-menu or parameters from up to down.

When the device is working, press this key to reduce speaker volume.

2.3.4. Confirming Key

When finishing selecting sub-menu and parameters, press this key to confirm the selected sub-menu and parameters.

2.3.5. Turning On/Off
Press once to turn on the device.
When the device is working, press this key for 3 seconds to turn off the device.

2.4 Indicating Lights

There are two indicting lights in main unit configuration.
2.4.1. Power Indicator Light
When turning on the device, the light is bright all the time.
2.4.2. Charge Indicator Light
When charging, it is orange colour. After finishing charging, it is green.

2.5 Work Modes

For any work modes, the FHR value is automatically displayed on LCD. There are these work modes as follows.
2.5.1. Real-Time Mode
In this mode, the heart symbol on LCD will flash, and real-time FHR is displayed on LCD.You can record or stop recording by pressing power On/Off key once.
2.5.2. Average Mode
This mode is used to get more stable heart rate value. The LCD displays the flashing heart symbol when displaying averaged FHR.
2.5.3. Manual Mode
This mode is used for FHR is not enough to display but heart beat can be audible.

Press power key, start to count. The LCD displays the flashing heart symbol and “---”. Press power key again after

the tenth heart beat, the device automatically calculates the derived FHR averaged and displays the FHR value. This rate value will keep till another measurement starts or the mode is changed.

2.5.4. Demo Mode

This mode displays the data which is stored in device.

2.6 Display Modes

There are three display modes as follows.

2.6.1. Curve Mode

Under this display mode, the device display FHR curve and relative parameters.

2.6.2. Large FHR Digit Mode

Under this display mode, the device display FHR value and relative parameters.

2.6.3. Large FHR Digit & Info

Under this display mode, the device display FHR value, main work parameters and other informations.

2.7 Parameters Explanation

Sub-Menu	Parameter	Explanation	Optional Value	Default Value
FHR setup	FHR volume	FHR volume	0-7	7
	Color	FHR color	ORANGE, GREEN, CYAN, PURPLE,	GREEN

			YELLOW, WHITE	
	Print speed	Print speed	1, 2, 3 cm/min	3 cm/min
	Print time	Automatic print time	00-60s, 00 is unlimited time	00
Alarm setup	Alarm	Alarm ON or OFF	ON, OFF	ON
	Upper limit	Alarm upper limit	60-210 bpm	180 bpm
	Upper limit	Alarm lower limit	60-210 bpm	120 bpm
	Delay time	Alarm delay time	5-20 S	10
Factory set	Factory set	Factory default set	YES, NO	NO
Display mode	Only curve	Display curve and other informations	/	YES
	Only number	Display FHR number and other informations	/	/
	Number & info	Display FHR, parameters, etc	/	/

Time setup	Year	Year	00-99	10
	Month	Month	1-12	01
	Day	Day	1-31	01
	Hour	Hour	00-23	12
	Minute	Minute	00-59	04
Work mode	Real time mode	Real time mode	/	YES
	Average mode	Average mode	/	/
	Manual mode	Manual mode	/	/
	Demo mode	Demo mode	ON, OFF	OFF
System set	Languag e	Language	ENGLISH , CHINESE	ENGLIS H

2.8 Probes

The basic probe frequency is 2MHz. 2.5MHz and 3MHz probe are optional.

Chapter 3 Basic Operation

3.1 Preparing to Use

Carefully check if the device has any damage and if the accessories are integrated. If so, please contact with manufacturer or local distributor immediately.

Keep the package for future transportation or storage.

3.2 Using Battery

3.2.1 Taking out battery

Turn the rear panel up. Hold the main unit with one hand. Press the battery cover with another thumb.

Then slide the cover along the arrow direction to take out battery.

3.2.2. Open the battery cover, put into the battery according to the sign direction.

3.2.3. Closing the Battery Compartment

Put the battery cover; slide the cover along the reverse direction of opening cover to close the battery compartment.

3.3 Operating Probes

3.3.1 Taking out and Inspecting the Probe

Hold the device main unit with one hand, hold the left part of the probe with another hand. Take out the probe along the left direction as follows.

On the contrary, you can easily fix the probe into probe clamp along the opposite direction of arrow.

When the device is power on, if the probe is not connected well with main unit, the LCD displays "— — —" and flash. After connecting well, LCD screen will stop flashing and display the probe frequency value.

3.3.2 Replacing Probe

Before replacing probe, please turn off the device.

Press the spring plate of crystal head, pull out the plug of the probe from its socket, then connect the probe you need to the socket.

3.4 Turning ON the Device

Turn on the device by pressing the power key once, the indicator light is bright.

3.5 Setting Parameter and Working Operation

1) Press **M** menu key to enter into menu set to set working parameters. Press ▲ up key and ▼ down key to select sub menu and parameter. Press ↵ confirmation key to confirm the selected sub menu and parameter. Finish setting the parameters, press **M** menu key to exit setting state and begin to work.
   The setting parameters are automatically saved.
   When working, press ▲ up key and ▼ down key to increase or reduce the volume.
2) At the bottom of screen, the work state is displayed.

3.6 Freezing, Storing and Playing Back

When working, press ❄ key to freeze the FHR or FHR curve on LCD will be freezed. This will keep till another measurement starts or the mode is changed.

Under freezing state, by pressing ▲ up or ▼ down key, the storage data can be played back with displaying FHR curve and time mark of 2 minutes length for every picture.

3.7 Turning OFF the Device

When the device is power on, press the key ⏻ again for 3 seconds to turn off the device.

NOTE: The device will automatically turn off in1 minute if it is not used.

3.8 Replacing or Charging the Battery

When the device warns the battery volume is not enough, please turn off the device and replace or charge the battery.

For charging the rechargeable battery in the machine, insert the DC plug into the device charge socket, and connect the device AC plug to the AC110-240V, 50/60Hz power supply.

It will take about 2 hours to fully charge the battery. When charging, the LED of the charger is orange; when the battery is fully charged, the LED turns to green.

⚠**CAUTION**⚠: When working, the rechargeable battery can not be recharged. You must turn off the Doppler before charging the battery.

⚠**CAUTION**⚠: The device can be used only when the charger is disconnected with the device.

⚠**CAUTION**⚠: Battery Disposal Recycle or dispose the battery should be in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

⚠**CAUTION**⚠: Charge the battery with the adaptor acCompanying with Doppler. Don't charge the battery over 12 hours.

Chapter 4 Inspecting and Recording

4.1 Gel Usage

Before placing the probe on the abdomen, apply ultrasound gel on the probe cover surface to reduce noise and improve test results.

4.2 Finding the Position of Fetus

Please feel the fetal position by hand. Place the probe on abdomen with feasible tight contact. The position for listening to fetal heart sounds is different at different gestational weeks. Pregnant mothers can find the correct position based on the gestational week and the fetal heart position chart, select the detection point, press gently for more than 10 seconds, and move the probe gently and slowly in a circular motion on the abdomen. Adjust the probe position to obtain an optimum audio signal. Wait until the sounds is clear and consecutive seconds later, the LCD screen will display the right FHR.

Reference map of fetal heart position

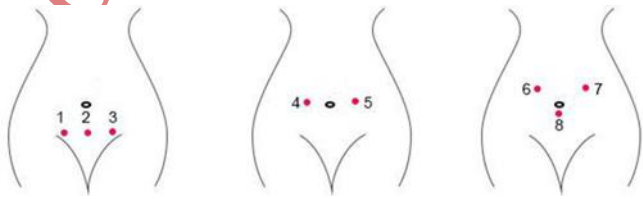

Figure 4.1

Early stage 12-24 Week, Mid-term 24-32 Week, Later period 32-40 Week. Before 24 weeks, the fetal heartbeat is usually found on the midline of the abdomen and on both sides of it. The shorter the pregnancy, the closer it is to the pubic bone.

24-32 weeks, the fetal heart rate is usually found on the midline of the abdomen or below the left and right sides of the navel. As the fetus grows, the position of the fetal heart rate will also move up. 32-40 weeks, the fetal heart rate is usually found above and below the navel. The fetal heart rate is usually on the other side of the fetal movement position.

NOTE: Do not compress probe too tightly on abdomen surface to avoid to weaken signal.

NOTE: When searching for the fetal heartbeat, do not pull the probe on the abdominal surface to avoid the noise.

NOTE: Do not put the probe on the position where there is strong Placental Blood Sound or strong Umbilical Sound.

4.3 FHR Inspecting

Finish setting mode and parameters, press power on/off key to start work, press power on/off key again to stop working.

NOTE: Do not measure FHR unless audible and identifiable fetal sound has been heard, usually it needs 5 seconds.

NOTE: The normal value of the fetal heart rate is 120-160bpm.100-120bpm and 160-180bpm is the critical values which should be paid some attention to. And lower than 100bpm and more than 180bpm are danger values which should be paid more attention to.

4.4 Adjusting Volume

When device is working, you can adjust volume by pressing ▲ or ▼ key to adjust volume.

4.5 Cleaning Work

After finishing using the device, please turn off the equipment in time and wipe the gel on the probe and skin, put the probe into the probe clamp.

Chapter 5 Cleaning and Disinfecting

5.1 Cleaning

Before cleaning the device, switch off and take out the battery from main unit.

Keep the outside surface of the device clean and free of dust and dirt. Clean exterior surface with a dry, soft cloth. Wipe off the remaining coupling agent on the probe then clean the probe at least 4-5 times slowly with a soft cloth soaked in alcohol (70%) and wipe dry with a clean cloth immediately. Dry it in a ventilated, cool place.

⚠CAUTION⚠:

Never use abrasive materials (such as steel wool or silver polish), or erosive cleansers (such as acetone or acetone-based cleaners). Do not allow any liquid to enter the case.

Do not immerse any part of the equipment into liquid.

Do not pour liquid onto the equipment or accessories.

Do not left any cleaning solution on the surface of the device.

Use only the substances approved by us and methods listed in this section to clean or disinfect your equipment. Warranty does not cover damages caused by unapproved substances or methods.

The remaining coupling agent (or gel) should be removed prior to the actual cleaning process.

5.2 Disinfecting

Clean the equipment case, probe, etc. as above, and then wipe the probe surface with an alcohol impregnated soft cloth (70% alcohol) at least 4-5 times with at least 3 cycles using a clean an alcohol impregnated soft cloth (70% alcohol).

Wipe the probe with a clean, dry cloth to remove any remaining moisture.

⚠CAUTION⚠:

Never use EtO or formaldehyde for disinfection.

Do not use low-temperature steam or other methods for sterilization.

Do not use high-temperature sterilization or radiation to disinfect the device.

CAUTION: Cleaning liquids: DO NOT submerge the device in liquids or pour cleaning liquids over, into or onto the device.

Chapter 6 Maintenance and Troubleshooting

6.1 Maintenance

The device is precision equipment, and the probe acoustic surface is frangible, you need to handle the device especially probe with enough care.

Gel and dirty dunghill must be wiped from the probe after using. These precautions will prolong the life of the unit and keep the examination precision.

Before using, the user must check that the equipment does not have visible evidence of damage that may affect patient safety or device capability. The recommended inspection interval is once per week. If damage is evident, reparation is recommended before use.

The device should undergo periodic safety testing to insure proper patient isolation from leakage currents. This should include leakage current measurement. The recommended testing interval is once every two years or as specified in the institution's test and inspection protocol.

The accuracy of FHR is controlled by the device and can not be adjusted by user. If the FHR result is distrustful, please use other method such as stethoscope to verify immediately or contact local distributor or manufacturer to get help. The device will be not calibration when suspicious of its accuracy.

6.2 Troubleshooting

When using, if it appears following problems. Please treat by following instruction. If fail to treat, please contact local distributor or manufacturer.

6.2.1 No Sound

Main reasons: (1) The battery volume is serious insufficient; (2) The equipment is damaged; (3) The battery connection line is damaged.

Solution: (1) Charge the battery or change battery; (2) Inspect the device; (3) Contact distributor or manufacturer.

6.2.2 Weak Sound

Main reasons: (1) Voice volume is too low; (2) Battery volume is too low; (3) Without or insufficient gel.

Solutions: (1) Adjust higher voice volume; (2) Change or charge the battery; (3) Add sufficient gel on probe inspecting surface.

6.2.3 Noise

Main reasons: (1) Probe is too near from the main unit; (2) Disturbance from the outside signal; (3) Battery volume is too low.

Solutions: (1) Keep the probe far enough from main unit; (2) Be away from outside signals; (3) Change or charge battery.

6.2.4 Low Sensitivity

Main reasons: (1) Probe position is incorrect; (2) Without or insufficient gel.

Solutions: (1) Keep the probe at right position; (2) Daub sufficient gel.

Chapter 7 Warranty and After-sale Service

7.1 Warranty

Manufacturer obligation under this warranty is limited to repair any part or whole unit upon manufacturer examination to prove they are within warranty period and range. If the product does not function during the warranty period, we will repair or replace it free of charge.

Limit of warranty:

1. Trouble resulting from misuse, negligence, accident or transportation.
2. Opening, modification or repairing by unauthorized persons from manufacturer.
3. Replacing or removing serial number label or manufacturer label.

7.2 After-sale Service

If you have any questions about use, maintenance, technical specifications or malfunction of device, please contact local distributor or manufacturer service department.

Chapter 8 Product Specifications

8.1 Product Name

Product Name: Pocket Fetal Doppler

8.2 Model

Model: SONOTRAX-E

8.3 Physical Characteristic

8.3.1 Size: 135 mm × 100 mm × 65 mm

8.3.2 Weight: About 65 gr (including battery)

8.4 Environment

8.4.1 Working:

Temperature: 5℃~40℃

Humidity: 25-80%

Atmospheric Pressure: 86~106KPa

8.4.2 Transport and Storage:

Temperature: -25℃~70℃

Humidity: ≤ 93%

Atmospheric Pressure: 70~106KPa

8.5 Display

Display: 65 mm ×50 mm LCD

8.6 Recommend Battery

3 pieces of 1.2V rechargeable battery

8.7 Performance Parameter

8.7.1 Working Frequency of Ultrasonic

Working frequency of ultrasonic is 2.0MHz (2.5MHz and 3.0 MHz optional), ±10%nominal standard

8.7.2 Overall Sensitive

200mm distance from probe, integrated sensitive≥90db

8.8 Working Mode

Working Mode: Continuous Wave Doppler

8.9 Measuring Performance

FHR Measuring Range: 50-230 bpm (beat per minute)

Resolution: 1bpm

Accuracy: ± 1bpm

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